

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (currently amended): A method for non-invasively determining a condition of the circulatory system of a subject, the subject inhaling and exhaling breathing gases during breathing, said method comprising the steps of:

- 5 (a) measuring the amount of CO₂ in the breathing gases exhaled by the subject and the CO₂ concentration of the breathing gases exhaled by the subject for a first (1) breathing condition of the subject;
- (b) determining at least one value of the amount of CO₂ released from the circulatory system of the subject (VCO₂¹) using the amount of CO₂ in the breathing gases exhaled when the subject is in the first condition;
- 10 (c) determining at least one value for a quantity indicative of the end capillary blood CO₂ content of the subject using the CO₂ concentration of the breathing gases exhaled when the subject in the first condition;
- (d) altering the CO₂ concentration in the lungs of the subject;
- (e) measuring the amount of CO₂ in the breathing gases exhaled by the
15 subject and the CO₂ concentration of the breathing gases exhaled by the subject for at least one breath of the subject under a second (2) breathing condition of altered CO₂ in the lungs of the subject;
- (f) determining at least one value for the amount of CO₂ released from the circulatory system of the subject (VCO₂²), the determination of the value being carried out in a
20 time period less than that required for blood leaving the lungs of the subject to pass through the circulatory system of the subject and return to the lungs, the determination of the value using the amount of CO₂ in the exhaled breathing gases for the second breathing condition;
- (g) determining at least one value for a quantity indicative of the end capillary
25 blood CO₂ content of the subject, the determination of the value being carried out in a time period less than that required for blood leaving the lungs of the subject to pass through the

circulatory system of the subject and return to the lungs, the determination of the value using the CO_2 concentration of the breathing gases exhaled for the second breathing condition;~~and~~

(h) performing a regression analysis using the determined VCO_2^1 , VO_2^2 , and end capillary blood CO_2 quantity values to establish a regression line;

30 (i) extrapolating the regression line to obtain a value for the end capillary blood CO_2 quantity when the amount of CO_2 released from the circulatory system of the subject (VCO_2) is zero;~~and~~

determining a further value for the quantity indicative of the end capillary blood CO_2 content for breathing of the subject in the first breathing condition;

35 forming a relationship between the value for the quantity indicative of the end capillary blood CO_2 content for breathing in the first breathing condition used in the regression analysis and the value obtained by extrapolating the regression line in step (i); and

applying the relationship to the further determined value for a quantity indicative of the end capillary blood CO_2 content to provide a new value for the value which was obtained
40 by the extrapolation of the regression line in step (i).

Claim 2 (original): The method according to claim 1 wherein steps (a) and (e) are further defined as measuring end tidal CO_2 concentrations of the breathing gases exhaled by the subject.

Claim 3 (original): The method according to claim 2 further defined in that the quantity, for which values are determined in steps (c) and (g), comprises the end tidal CO_2 concentration of the exhaled breathing gases and that the value obtained in step (i) is the end tidal CO_2 concentration when the amount of CO_2 released from the circulatory system of the subject
5 (VCO_2) is zero.

Claim 4 (original): The method according to claim 1 further defined in that the quantity, for which the values are determined in steps (c) and (g), comprises the CO_2 partial pressure in the blood of the subject and that the value obtained in step (i) is the CO_2 partial pressure of the end

capillary blood of the subject when the amount of CO_2 released from the circulatory system of
5 the subject (VCO_2) is zero.

Claim 5 (original): The method according to claim 1 or 2 further defined in that the quantity, for
which the values are determined in steps (c) and (g), comprises the CO_2 content of the end
capillary blood (CcCO_2) of the subject and that the value obtained in step (i) is the CO_2 content
of the end capillary blood of the subject when the amount of CO_2 released from the circulatory
5 system of the subject (VCO_2) is zero, which value comprises the CO_2 content of venous blood
(CvCO_2).

Claim 6 (previously presented): The method according to claim 1 further including the step
of using the value obtained in step (i) to determine the functional cardiac output (FCO) of the
subject using a non-differential form of the Fick equation.

Claim 7 (previously presented): The method according to claim 1 further defined as including
the steps of:

determining further values for the amount of CO_2 released from the circulatory
system of the subject (VCO_2) and for the quantity indicative of the end capillary blood CO_2
5 content for breathing of the subject in the first breathing condition; and

using the value provided by the extrapolation of the regression line in step (i) and
a further determined released CO_2 amount (VCO_2) and value for the quantity indicative of end
capillary blood CO_2 content to determine the functional cardiac output of the subject using a
non-differential form of the Fick equation.

Claim 8 (original): The method according to claim 7 further defined as being carried out on a
breath-by-breath basis.

Claim 9 (canceled)

Claim 10 (previously presented): The method according to claim 1 further defined as forming a relationship comprising as a ratio.

Claim 11 (previously presented): The method according to claim 1 further defined as forming a relationship comprising a difference.

Claim 12 (previously presented): The method according to claim 1 further including the steps of:

determining further values for the amount of CO₂ released from the circulatory system of the subject (VCO₂^N) for breathing of the subject in the first breathing condition; and
5 using the further determined released CO₂ amount (VCO₂¹), the further determined value for a quantity indicative of the end capillary blood CO₂ content, and the new value for the value which was obtained by extrapolation of the regression line in a non-differential form of the Fick equation to determine the functional cardiac output (FCO) of the subject.

Claim 13 (previously presented): The method according to claim 1 further defined as being carried out on a breath-by-breath basis.

Claim 14 (original): The method according to claim 1 wherein the step of altering the CO₂ concentration in the lungs of the subject is further defined as increasing the CO₂ concentration in the lungs of the subject to reduce CO₂ gas exchange in the lungs of the subject.

Claim 15 (original): The method according to claim 14 wherein the step of increasing the CO₂ concentration in the lungs of the subject is further defined as increasing the CO₂ content of the breathing gases inhaled by the subject.

Claim 16 (original): The method according to claim 15 further defined as administering a bolus of CO₂ into the breathing gas inhaled by the subject.

Claim 17 (original): The method according to claim 15 further defined as causing the subject to inhale breathing gas previously exhaled by the subject.

Claim 18 (original): The method according to claim 15 wherein step (d) is further defined as increasing the CO_2 by an amount which improves the accuracy of the determination while avoiding undue build up of CO_2 in the blood of the subject.

Claim 19 (original): The method according to claim 1 wherein the step of altering the CO_2 concentration in the lungs of the subject is further defined as decreasing the CO_2 concentration in the lungs of the subject to increase CO_2 gas exchange in the lungs of the subject.

Claim 20 (original): The method according to claim 19 wherein the step of decreasing the CO_2 concentration in the lungs of the subject is further defined as increasing the ventilation of the subject.

Claim 21 (original): The method according to claim 5 further defined as including the steps of :
determining the amount of oxygen in the venous blood of the subject; and
altering the obtained value for the venous blood CO_2 content (CvCO_2) in
accordance with the amount of oxygen in the blood to provide a CO_2 partial pressure value
5 (PvCO_2) for venous blood.

Claim 22 (original): The method according to claim 21 wherein the step of the determining the amount of oxygen in the venous blood is further defined as determining the degree of oxygen saturation of the venous blood.

Claim 23 (original): The method according to claim 21 further defined as including the steps of:
determining a further value for the quantity indicative of the end capillary blood
 CO_2 content for breathing of the subject in the first breathing condition;

forming a relationship between the value for the quantity indicative of the end
5 capillary blood CO₂ content for breathing in the first breathing condition used in the regression
analysis and the CvCO₂ value obtained by extrapolating the regression line in step (i);
applying the relationship to the further determined value for a quantity indicative
of the end capillary blood CO₂ content to provide a new CvCO₂ value; and
altering the new CvCO₂ value in accordance with the amount of oxygen in the
10 blood to provide a new CO₂ partial pressure value (PvCO₂) for venous blood.

Claim 24 (original): The method according to claim 23 further defined as forming a relationship
comprising a ratio.

Claim 25 (original): The method according to claim 23 further defined as forming a relationship
comprising a difference.

Claim 26 (previously presented): The method according to claim 21 further defined as carrying
out the method on a breath-by-breath basis.

Claim 27 (previously presented): The method according to claim 1 further defined as
performing linear regression analysis using the VCO₂¹, VO₂², and values for the quantity
indicative of the end capillary blood CO₂ content of the subject determined using the exhaled
breathing gas CO₂ concentrations for the first and second conditions.

Claim 28 (original): The method according to claim 1 where the breathing gases supplied to the
subject comprise air.

Claim 29 (original): The method according to claim 1 further including the step of allowing the
subject to take a sufficient number of breaths to stabilize the CO₂ content and CO₂ concentration
of the exhaled breathing gases before taking the breathing measurements for the first breathing
condition of the subject.

Claim 30 (previously presented): The method according to claim 1 further defined as determining a plurality of values for at least one of the amount of CO₂ released from the circulatory system of the subject (VCO₂) and the quantity indicative of the end capillary blood CO₂ content for use in performing the regression analysis.

Claim 31 (original): The method according to claim 1 wherein steps (b) and (f) are further defined as determining at least one value of the amount of CO₂ released from the circulatory system of the subject (VCO₂) using the CO₂ content of the inhaled and exhaled breathing gases.

Claim 32 (currently amended): A method for determining a change in a measured condition of the circulatory system of a subject, said method comprising the steps of:

- (a) non-invasively obtaining, from the subject, an initial value for at least one selected variable comprising at least one of exhaled CO₂ amount, end tidal CO₂ amount, heart rate, and the amount of CO₂ released from the circulatory system of the subject (VCO₂);
- (b) carrying out a discrete measurement of a circulatory system condition of a subject;
- (c) obtaining a further value for the at least one selected variable subsequent to carrying out the discrete measurement;
- (d) comparing the ~~subsequent~~ further value of the variable with the initial value of said variable to determine whether the obtained variable has changed in value; and
- (e) initiating a carrying out of a further discrete measurement of a circulatory system condition of the subject responsive to a change in the value of the variable.

Claim 33 (canceled)

Claim 34 (previously presented): The method according to claim 32 further defined as compensating the values of the selected variable for changes in the condition of the subject not arising from circulatory system conditions.

Claim 35 (previously presented): The method according to claim 34 further defined as compensating a selected variable for changes in ventilation of the subject.

Claim 36 (previously presented): The method according to claim 32 wherein the discrete measurement of circulatory system condition in steps (b) and (e) is carried out using a non-differential form of the Fick Equation and the quantities expressed therein and the circulatory system condition is the functional cardiac output (FCO).

Claim 37 (previously presented): The method according to claim 32 wherein the discrete measurement of circulatory system condition in steps (b) and (e) is carried out using a differential form of the Fick Equation and the quantities expressed therein.

Claim 38 (previously presented): The method according to claim 37 wherein the at least one selected variable further comprises at least one of the amount of CO₂ released from the circulatory system of the subject (VCO₂) and the end tidal CO₂ amount for normal conditions of the subject.

Claim 39 (original): The method according to claim 37 wherein the measured circulatory system condition is functional cardiac output (FCO).

Claim 40 (currently amended): The method according to claim 32 wherein the discrete ~~measurement~~ measurements of circulatory system condition are carried out using the quantities expressed in a differential form of the Fick Equation and the circulatory system condition is venous blood partial CO₂ pressure (PvCO₂).

Claim 41 (previously presented): The method according to claim 39 wherein the at least one selected variable further comprises at least one of the amount of CO₂ released from the circulatory system of the subject (VCO₂) and end tidal CO₂ for normal conditions of the subject.

Claim 42 (original): The method according to claim 32 wherein the discrete measurement of the circulatory system condition in step (b) is carried out using a blood dilution technique.

Claim 43 (original): The method according to claim 42 wherein the blood dilution technique uses a marker dye.

Claim 44 (original): The method according to claim 42 wherein the blood dilution technique uses thermodilution.

Claim 45 (original): The method according to claim 42 wherein the circulatory system condition measured is cardiac output (CO).

Claim 46 (previously presented): The method according to claim 32 wherein step (c) is further defined as sequentially obtaining further values of the at least one selected variable for comparison with the initial value.

Claim 47 (original): The method according to claim 46 further defined as obtaining further values on a breath-by-breath basis.

Claim 48 (original): The method according to claim 46 further defined as obtaining further values on a heart beat by heart beat basis.

Claim 49 (previously presented): The method according to claim 32 further defined as allowing disturbances caused by the carrying out of the discrete measurement to subside before obtaining a further value for said at least one selected variable.

Claim 50 (previously presented): The method according to claim 37 further defined as allowing disturbances caused by the carrying out of the discrete measurement to subside before obtaining a further value for said at least one selected variable.

Claim 51 (previously presented): The method according to claim 32 wherein step (d) is further defined as determining whether the variable has changed by a predetermined amount.

Claims 52-53 (canceled)

Claim 54 (previously presented): The method according to claim 32 further defined as providing an indication that a change in the value of the variable has occurred.

Claim 55 (previously presented): The method according to claim 32 further defined as providing an indication of the amount by which the value of the variable has changed.

Claim 56 (previously presented): The method according to claim 32 further defined as providing an indication of the direction in which a change in the value of the variable has occurred.

Claim 57 (previously presented): The method according to claim 32 further defined as providing an alarm.

Claim 58 (currently amended): Apparatus for determining a change in a measured condition of the circulatory system of a subject, said apparatus comprising:

- 5 (a) means for non-invasively obtaining, from the subject, an initial value and subsequent value for at least one selected variable comprising at least one of exhaled CO₂ amount, end tidal CO₂ amount, heart rate, and the amount of CO₂ released from the circulatory system of the subject (VCO₂);

(b) means for carrying out a discrete measurement of a circulatory system condition of a subject;

10 (c) means for comparing the subsequent value of the variable with the initial value of said variable to determine whether the obtained variable has changed in value and for causing said means for carrying out a discrete measurement to carry out a further discrete measurement of a circulatory system condition of the subject responsive to a change in the value of the variable.

Claim 59 (canceled)

Claim 60 (previously presented): The apparatus according to claim 58 further defined as including means for compensating the values of the selected variable for changes in the condition of the subject not arising from circulatory system conditions.

Claim 61 (original): The apparatus according to claim 58 wherein the measured circulatory system condition is functional cardiac output (FCO).

Claim 62 (original): The apparatus according to claim 58 wherein the measured circulatory system condition is venous blood partial CO₂ pressure (PvCO₂).

Claim 63 (original): The apparatus according to claim 58 wherein the measured circulatory system condition is cardiac output.

Claim 64 (original): The apparatus according to claim 58 wherein the circulatory system condition is measured non-invasively.

Claim 65 (original): The apparatus according to claim 58 wherein the circulatory system condition is measured invasively.

Appln. No. 10/091,169
Amendment dated March 15, 2006
Reply to Notice of Allowance of December 20, 2005

Claim 66 (canceled)

Claim 67 (previously presented): The method according to claim 3 further including the step of using the value obtained in step (i) to determine the functional cardiac output (FCO) of the subject using a non-differential form of the Fick equation.

Claim 68 (previously presented): The method according to claim 4 further including the step of using the value obtained in step (i) to determine the functional cardiac output (FCO) of the subject using a non-differential form of the Fick equation.

Claim 69 (previously presented): The method according to claim 5 further including the step of using the value obtained in step (i) to determine the functional cardiac output (FCO) of the subject using a non-differential form of the Fick equation.